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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,023	09/29/1999	HARASH KUMAR NARANG	0769.00125	3494

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/408,023	Applicant(s) NARANG, HARASH KUMAR	
	Examiner Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on 5-10-2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 5-10-2002 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed on 3-19-2002 has been entered. Claims 1-3, 5-9, 11-13, 15-17, 19-21 and 24-29 have been canceled. Claims 44-47 have been amended. Claims 44-47 are pending and currently under examination.

Objections Maintained

Specification

The objection to the use of the trademark Tween is maintained for reasons of record.

Claim Rejections Withdrawn

35 USC § 112

The rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 44-47 under 35 U.S.C. 112, second paragraph, for the use of the term "such as " is withdrawn in light of the amendment thereto.

The rejection of claims 1-21, 24-33 and 37-43 under 35 U.S.C. 103(a) as being unpatentable over Schenk et al. (U.S. Patent 5,593,846), in view of Alaska et al. (U.S. Patent 5,744,587) and Chu et al. (U.S. Patent 4,604,208) is withdrawn. Cancellation of said claims has rendered the rejection moot.

Claim Rejections Maintained and New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The aforementioned claims recite methods for monitoring liquids for the presence of disease-modified or associated proteins comprising of the steps concentrating the proteins (and associated DNA) by contacting a solid non-buoyant particulate material having free ionic valencies and subsequently monitoring the concentrated protein/DNA via conventional assays including: polymerase chain reaction (PCR), restriction fragment length method (RFLP) and Southern blotting. While applicant recites the conventional assays in sufficient detail for one of skill in the art to perform them in general, Applicant fails to describe the claimed invention in sufficient detail to enable one of skill in the art to make and use said invention. The specification

discloses that the disease-modified or associated proteins in a biological fluid (urine) are concentrated by the addition of granular calcium phosphate and a "suitable buffer". Only granular calcium phosphate was given as an example the solid non-buoyant particulate material However, Applicant fails to describe what quantity or purity of calcium phosphate is required to practice the said invention and does not describe what exemplifies a "suitable buffer" or what volume and/or molarity is required for use in the claimed invention. Applicant does describe the use of "non-buoyant particulate flock" (see page 21) but provides no information on what it is, where it could be obtained, or how to make it. Consequently, it would require undue experimentation by one of skill in the art to make and use the claimed invention.

Claims 46-47 specifically recite the use of the aforementioned inventions to monitor urine for the presence of disease-modified or associated proteins, protein fragments, viruses, or virus fragments. Applicant, however fails to describe what particular proteins or viruses would be present in the liquid; or what specific reagents (i.e. antibodies etc.) would be needed to detect said proteins and viruses or how to associate them with particular diseases. Insofar as can be determined, the art does not teach the presence of disease-modified or associated proteins or viruses in urine to be associated with the diseases as claimed by applicant. Hence, it would require undue experimentation by one of skill in the art to make and/or use the claimed invention as described.

Claims 43-47 recite the amplification of concentrated proteins/DNA by PCR and subsequent monitoring by a restriction fragment length method. The aforementioned methods require nucleic acids not protein for their practice. The specification is silent on what proteins have DNA associated with them, how DNA that is "associated with a disease modified protein or

virus" is distinguished from other DNA. The specification is equally silent on what primers are to be used in the PCR reaction or which restriction enzymes are to be used in the RFLP methods. Consequently, since the specification does not teach how to perform PCR/RFML using protein associated DNA it is not enabled.

Additionally, the rejected claims recite use of DNA associated with concentrated proteins in a hybridization reaction and subsequently monitored using Southern blotting hybridization. The specification does not describe what "hybridization reaction" is to be used or how to perform said reaction and hence the claim is not enabled.

Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The aforementioned claims recite methods for monitoring liquids for the presence of disease-modified or associated proteins comprising of the steps concentrating the proteins (and associated DNA) by contacting a solid non-buoyant particulate material having free ionic valencies and subsequently monitoring the concentrated protein/DNA via conventional assays including: polymerase chain reaction (PCR), restriction fragment length method (RFLP) and Southern blotting. While applicant recites the conventional assays in sufficient detail for one of skill in the art to perform them in general, Applicant fails to describe the claimed methodology (i.e. amplification of DNA via PCR and analysis via RFLP and Southern blotting hybridization) in a manner that would allow one of skill in the art to use the claimed invention. Additionally,

Applicant provided any correlation between amplified DNA and disease modified or associated proteins.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: concentrating and washing the granular calcium phosphate particles to remove unbound materials.

Claims 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 44-47 is it not clear how the recited steps of DNA amplification, RFLP ad Southern blotting hybridization correlate to a method of "monitoring" a liquid for the presence of disease modified or associated proteins. Said methodologies render themselves to the detection of DNA not proteins.

Claims 44 and 46-47 are rendered vague and indefinite by the use of the term "restriction fragment length method". It is unclear what method Applicant is referring to. Is said phrase

referring to restriction fragment length polymorphism? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 44-47 are rendered vague and indefinite by the use of the phrase "said amplified DNA material in a Southern blotting hybridization assay". It is unclear whether said DNA material was used in a Southern blotting hybridization assay as an alternative to the restriction fragment length method or subsequent to it.

Claim 45 recites the limitation "amplified DNA" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claims 46-47 recite improper Markush language. When the phrase "selected from the group consisting of" is used the ultimate member of the recited group must be preceded by the conjunction "and". Additionally, the use of the conjunction "or" multiple times with in the listed groups makes it impossible to determine what Applicant is claiming as members of the Markush group.

Claims 46-47 are rendered vague and indefinite by the use of the phrase "monitoring at least part of the complexed biological material". It is unclear what is meant by said phrase. What part other than the DNA associated with the complexed disease modified or associated proteins can be monitored utilizing the recited methods?

Claims 46-47 are rendered vague and indefinite by the use of the phrase "presence of said biological material is indicative of an association of said liquid with the relevant disease". It is not clear what is meant by said phrase. For example, if a given protein was found in urine is Applicant stating that urine is associated with a disease just because said protein was isolated from it? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
July 24, 2002